

In response to the Restriction Requirement, applicants hereby elect without traverse Group I, drawn to polypeptide compositions concerning claims 1-4 and 9. applicants reserve the right to file a divisional application to the nonelected claims of Group II, III, and IV.

Please amend the application as follows:

In the Specification:

- ✓ at page 34, line 19 after "No." please insert --VR 2411--.
- ✓ at page 47, line 17 under the heading of Accession No. for *Autographa californica nuclearpolyhedrosis virus* KGF-5 please insert --VR 2411--.

Remarks

Introduction

Claims 1-4, and 9 are currently pending in the above-identified application. Applicants submit that the pending claims are allowable in light of the amendments and remarks and request withdrawal of the Examiner's rejections.

Amendments

The specification has been amended to indicate the ATCC accession numbers of the deposited materials. No new matter has been added by these amendments. Entry thereof is respectfully requested.

Objection to the Specification and Rejection of claim 4 under 35 U.S.C. § 112, First Paragraph

The specification has been objected to and claim 4 has been rejected as the Office Action alleges that the specification "fails to teach ... how to make and use KGF

fragments or analogs exhibiting decreased cytotoxicity." Applicants respectfully traverse. Applicants have set forth several methods of how to make and prepare KGF_{des1-23} in the specification; *see, for example*, page 11, lines 5-8 and lines 19-29 continuing onto page 12, lines 1-22. This molecule, designated by applicants as KGF_{des1-23}, inherently possesses properties of decreased cytotoxicity and increased mitogenic activity when compared to full-length KGF or aFGF while retaining the ability to stimulate epithelial cell proliferation; *see, for example*, page 15, lines 7-13, page 37, lines 3-5, and Figure 4.

Applicants have also indicated potential uses of KGF_{des1-23} in wound healing applications as well as in the treatment of hyperproliferative disease of the epidermis, such as psoriasis and basal cell carcinoma, *see for example* page 2 lines 22-26, and page 13, lines 6-10. Hence, applicants have provided sufficient teaching under 35 U.S.C. § 112, first paragraph for making and using a KGF fragment having decreased cytotoxicity. The Official Action has failed to establish otherwise.

In light of the above remarks, a request for withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully made.

Rejection of claims 1-3 and 9 under 35 U.S.C. § 112, First Paragraph

Claims 1-3 and 9 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that "no other KGF fragments have been demonstrated to exhibit the increased mitogenic activity" and, furthermore, that "no analogs of KGF fragments have been fully described or analyzed for biological activity". Applicants respectfully traverse this rejection.

The specification at, for example, page 6, lines 10-18 defines the "KGF fragment." The specification at, for example, page 6, line 9 continuing onto page 7, line 7 defines the "analog of the KGF fragment." As referenced above, the specification clearly teaches how to make and use the KGF fragment. The Official Action has failed to establish that a person skilled in the art, following applicant's teaching herein would be unable to

make and use the analogs being claimed. Clearly, for example, amino acid insertions, deletions, or substitutions are within the skill of persons in the art, as well as testing biological activity. Applicants point out that some experimentation is not detrimental to enablement. The burden of proof demonstrating lack of enablement unquestionably rests with the Examiner.

In light of the above remarks, a request for withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully made.

Conclusion

Applicants respectfully submit the foregoing amendments and remarks. Please place the application in condition for allowance and request a Notice of Allowability thereof.

If the Examiner believes that a telephone interview would expedite prosecution of this application, the Examiner is invited to contact the undersigned at (510) 601-2768.

Respectfully submitted,

CHIRON CORPORATION

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